

## Claims

What is claimed is:

1. A method for detecting epithelial dysplasia comprising the steps of: taking a non-lacerational trans-epithelial sample of epithelial tissue and then analyzing the sample with a molecular diagnostic technique.
2. A method as claimed in Claim 1, wherein said technique includes, but is not limited to, fluorescence and non-fluorescence in situ hybridization, loss of heterozygosity, clonal genetic alterations, PCR, p53 expression and the expression pattern of CD44 variant 6 protein by immunohistochemistry, monoclonal antibodies reactivity patterns, glutathione S-transferase activity, measuring the number of nucleolar organizer regions, and cell-cycle and proliferation markers such as the centromere-associated protein.
3. A method as claimed in Claim 1, wherein said trans-epithelial sample of epithelial tissue is examined for abnormalities in cellular morphology and abnormalities in keratinization.
4. A method as claimed in Claim 1, wherein said trans-epithelial sample of epithelial tissue is examined for abnormalities using computer-assisted analysis.
5. A method for detecting epithelial dysplasia comprising the steps of:
  - (a) examining said trans-epithelial sample of epithelial tissue for abnormalities in

cellular morphology and abnormalities in keratinization;

(b) and then analyzing the sample with a molecular diagnostic technique.

6. A method as claimed in Claim 5, wherein said technique includes, but is not limited to, fluorescence or non-fluorescence in situ hybridization, loss of heterozygosity, clonal genetic alterations, PCR, p53 expression and the expression pattern of CD44 variant 6 protein by immunohistochemistry, monoclonal antibodies reactivity patterns, glutathione S-transferase activity, measuring the number of nucleolar organizer regions and cell-cycle and proliferation markers such as the centromere-associated protein.
7. A method as claimed in Claim 5, wherein said trans-epithelial sample of epithelial tissue is examined for abnormalities using computer-assisted analysis.
8. A method for detecting precancerous and cancerous cells comprising:
  - (a) analyzing a population of cells to determine the most suspect cells therein; and
  - (b) conducting a ploidy analysis on said most suspect cells on a cell by cell basis.
9. The method of claim 8, wherein said analyzing said population of cells is conducted by computer analysis.
10. The method of claim 9, wherein said population of cells are harvested from tissue from a human.
11. The method of claim 10, wherein said population of cells are harvested from epithelial tissue.
12. The method of claim 11, wherein said population of cells are harvested from the superficial, intermediate and basal cell layers.
13. The method of claim 12, wherein said population of cells are obtained by use of a non-lacerational biopsy.
14. The system of claim 8, wherein said atypical cells are further distinguished with a molecular diagnostic technique.
15. A method of enhancing cancerous cell diagnosis of a population of cells which have

been identified as having suspect cancerous cells, said method comprising conducting ploidy analysis on said suspect cancerous cells on a cell by cell basis.

16. A system to detect cancerous and precancerous cells in a cell population comprising:
  - (a) a computer to morphologically analyze individual cells for atypicality;
  - (b) said computer cytometrically analyzing said individual cells for atypicality; and
  - (c) selecting said individual cells exhibiting atypical cytometry and morphology in order to conduct DNA ploidy quantization.
17. The system of claim 16, wherein said cancerous and precancerous cells are examined for abnormalities using computer assisted analysis.
18. The system of claim 17, wherein the location of said cells exhibiting both atypical morphology and cytometry are retrieved by said computer for DNA ploidy analysis by a pathologist on a cell by cell basis.
19. The system of claim 18, wherein a histogram is plotted based of the DNA ploidy of said cell population.
20. The system of claim 18, wherein said atypical cells are selected based on reference cells chosen from the same population.
21. The system of claim 19, wherein said histogram has a light indicator to further indicate the DNA ploidy of said atypical cell during final analysis by a pathologist.
22. The system of claim 21, wherein the final interpretation of the image analysis histogram is conducted in conjunction with the patient's history, biopsy findings, or any other pertinent test results.
23. The system of claim 16, comprising the further distinction of said cells with molecular diagnostic techniques.

**Diagram 1**

Taking a trans-epithelial sample of epithelial tissue



Examining said trans-epithelial sample of epithelial tissue for abnormalities in cellular morphology and abnormalities in keratinization and/or examining said sample of epithelial tissue for abnormalities using computer-assisted analysis, including but not limited to the machines and/or techniques of the '218 and/or '219 applications.



Analyzing the sample with a molecular diagnostic technique, said technique including but not limited to, fluorescence in situ hybridization, loss of heterozygosity, clonal genetic alterations, PCR, p53 expression and the expression pattern of CD44 variant 6 protein by immunohistochemistry, monoclonal antibodies reactivity patterns, glutathione S-transferase activity, measuring the number of nucleolar organizer regions and cell-cycle and proliferation markers such as the centromere-associated protein.

**Diagram 2**

Taking a trans-epithelial sample of epithelial tissue

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Examining said trans-epithelial sample of epithelial tissue  
for abnormalities in cellular morphology, and DNA concentration  
and/or examining said sample of epithelial  
tissue for abnormalities using computer-assisted analysis,  
including but not limited to the machines and/or  
techniques of the '218 and/or '219 applications.

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Analyzing the sample for a DNA ploidy analysis, said DNA ploidy determination being  
conducted by a pathologist.

**Diagram 3**

Taking a trans-epithelial sample of epithelial tissue

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Examining said trans-epithelial sample of epithelial tissue for abnormalities in cellular morphology, keratinization and DNA concentration and/or examining said sample of epithelial tissue for abnormalities using computer-assisted analysis, including but not limited to the machines and/or techniques of the '218 and/or '219 applications.

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Analyzing the sample with a molecular diagnostic technique and/or for a DNA ploidy analysis, said DNA ploidy determination being conducted by a pathologist and said molecular diagnostic technique including but not limited to, fluorescence in situ hybridization, loss of heterozygosity, clonal genetic alterations, PCR, p53 expression and the expression pattern of CD44 variant 6 protein by immunohistochemistry, monoclonal antibodies reactivity patterns, glutathione S-transferase activity, measuring the number of nucleolar organizer regions and cell-cycle and proliferation markers such as the centromere-associated protein.